Highmark's Weekly Capitol Hill Report

Issues for the week ending June 18, 2021

Federal Issues

Legislative

Congress Examines COVID-19 Vaccine Legislation, Mental Health

Last week, two committees on Capitol Hill held hearings on key health issues facing the nation, including COVID-19 and mental health:

- House Energy and Commerce (E&C) Committee: On Tuesday, the E&C Subcommittee on Health held a legislative hearing titled, "Booster Shot: Enhancing Public Health through Vaccine Legislation." Lawmakers discussed 12 bills during the hearing, including a proposal to ensure that all Medicare Part D covered vaccines recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) have no beneficiary cost-sharing.

  Health care policymakers and industry stakeholders testified before the subcommittee about the importance of the CDC's Vaccines for Children (VFC) program, which provides low-income children with access to vaccines, and routine vaccinations for preventable

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diseases, which have dropped significantly since the start of the COVID-19 pandemic.

- Senate Finance Committee: On Tuesday, the Senate Finance Committee met for a hearing on "Mental Health Care in America: Addressing Root Causes and Identifying Policy Solutions." In his opening remarks, Chairman Ron Wyden (D-OR) urged health insurance companies not to "cut corners when it comes to mental health coverage" and called on the Committee to work on racial inequities in mental health care.

  Ranking Member Mike Crapo (R-ID) used his opening remarks to speak about the importance of state Medicaid programs in providing mental health and substance use disorder services and recommended that lawmakers grant states additional flexibilities. Sen. Crapo also highlighted the benefits of telehealth services in connecting people from rural, urban and tribal areas with needed health care.

Pennsylvania
Legislative

- **House Committee Examines Claims Data Sharing for Groups 51-100**

Federal Issues

Regulatory

Supreme Court Again Upholds Affordable Care Act

The U.S. Supreme Court issued a 7-2 decision directing the dismissal of the ACA lawsuit (*California v. Texas*) on grounds that the individual states who challenged the law lacked standing to bring suit.

Why this matters: The decision, authored by Justice Breyer, effectively preserves the ACA as the law of the land.

Notably, the decision did not address the questions of whether: 1) the ACA's now zeroed-out individual mandate penalty is constitutional; and 2) the related "severability" question of whether any other provisions of the ACA would survive were the zeroed-out individual mandate provision found to be unconstitutional. Instead, the Court found that the state and individual plaintiffs each "failed to show a concrete, particularized injury fairly traceable to the defendants' conduct in enforcing the specific statutory provision they attack as unconstitutional" and therefore lacked standing to bring suit. The Court directed the case be

sent back down (*i.e.* remanded) to the U.S. Court of Appeals for the Fifth Circuit (and ultimately the Federal District Court for the Northern District of Texas) and dismissed.

Insurer Perspective: "We believe the Supreme Court rightly concluded this case does not belong in court, as the challengers have not suffered any injury. The ACA remains the law of the land and a foundational component of health care and coverage for more than 300 million Americans. After a year filled with unprecedented loss when reliable comprehensive health coverage has never been more important, this decision protects the stability of health coverage for people with pre-existing conditions, hardworking families, seniors, and other Americans who need it most. With more than one million more people having already signed up for coverage during this special enrollment period and millions more receiving their care through the ACA's Medicaid expansion, it is clear that Americans agree we should continue to build on the ACA to improve coverage and care for everyone," stated Matt Eyles, president and CEO of AHIP.

Biden Administration Releases First Unified Agenda of Regulatory and Deregulatory Actions

The White House Office of Management and Budget (OMB) posted the 2021 Spring regulatory agenda. The Department of Health and Human Services (HHS) incorporated several Medicare Advantage proposed rules in the agenda, including:

- Policy and technical changes for Contract Year 2023
- The codification of MA and Part D payment policies outside the scope of the annual Advanced Notice/Rate Announcement
- A final rule on risk adjustment data validation provisions
- Proposed rulemaking on a mandatory Alternative Payment Model, which would be piloted through CMS's Innovation Center (CMMI) and intended to reduce Medicare expenditures.

With regards to the Medicaid program, HHS propose several rules, including but not limited to:

- A rule that would expand the prohibition on adding/modifying a risk mitigation arrangement to prospective Medicaid managed care contract rating periods
- A rule to streamline eligibility and enrollment processes
- The establishment of mandatory requirements for Medicaid and CHIP Core Set Reporting

Following a recent Executive Order, the Department of Homeland Security will publish an advance notice of proposed rulemaking and re-define the term "public charge."

Impacting the commercial market related to the No Surprises Act (NSA), HHS intends to:

- Issue an interim final rule to address Surprise Billing Protections
- Issue a second interim final rule to address the Independent Dispute Resolution process
- Propose an enforcement rule regarding Air Ambulance Reporting Requirements and Agent and Broker compensation information
- Propose a rule regarding Provider Nondiscrimination Requirements

Finally, HHS's Office of Civil Rights will propose changes the 2020 Final Rule implementing the ACA's Section 1557 nondiscrimination policies.

Why this matters: Implementation of the Consolidated Appropriations Act, 2021, such as the No Surprises Act, provider nondiscrimination standards, and prescription drug reporting, is another major theme for regulatory activity in the short-term and is not surprising given the statutory deadlines for implementing many provisions..

HHS Proposes Withdrawal of Health Center Drug Discount Rule

As expected, the HHS Health Resources and Services Administration (HRSA) issued a proposed rule to rescind the final rule requiring federal health care centers to provide certain insulin and epinephrine medications at or below the price the health center purchased them through the 340B drug discount program. The final rule, currently delayed to July 20, 2021, was called for by a Trump administration Executive Order. The rule's required discounts would be available for individuals with incomes at 350% of the federal poverty level or below if they are uninsured or have high out-of-pocket costs.

HRSA cites the ongoing challenges from the COVID-19 pandemic's demand on health centers raised by commenters in justifying the rescission of the rule. It also cites a loss of revenue expected from the rule, which will decrease patient services and access to care. Finally, HRSA notes that in many cases, health centers already provide medications at reduced prices to their patients.

Comments to the proposed rule are due July 16, 2021.

New Studies Highlight How Out-of-Control Drug Prices Are Harming Care and Coverage for Millions of Americans

Two new studies show how out-of-control drug prices are putting health care coverage out of reach for millions of Americans.

First, the Medicare Payment Advisory Commission's (MedPAC) June report to Congress noted Medicare spending on Part D drugs surged 26% between 2013 and 2018. The bulk of the growth was directly tied to higher drug prices, as opposed to any increases in the number of prescriptions filled by enrollees. The price increases were largely associated with drugs launched after 2013, the report found.

High drug prices were similarly spotlighted in a *Health Affairs* study, which found Part D's share of annual spending on drugs with very high prices increased by 1,170% between 2012 and 2018. The study noted that 61 "ultra-expensive" drugs entered the market between 2012 and 2018. Drugs were categorized as ultra-expensive when the average annual per enrollee spending by Medicare and enrollee exceeded the annual U.S. per capita GDP. The U.S. GDP per capita was $62,996 in 2018. As more ultra-expensive drugs hit the market, Part D patients will face higher cost sharing, the study said.

EEOC Workplace Wellness Program Rules Unlikely in 2021

Federal regulations governing incentives available under workplace wellness programs have been under development at the Equal Employment Opportunity Commission (EEOC) for the past few years. No revised rules are likely until new commissioners are appointed by the Biden Administration in mid-2022.

Why this matters: In January 2018, the U.S. District Court for the District of Columbia vacated the EEOC's 2016 final rules for workplace wellness programs, finding the EEOC's rules for wellness programs incentives were arbitrary and could not be justified under the Americans with Disabilities Act (ADA) and Genetic Information Nondiscrimination Act (GINA). The rules were vacated effective January 1, 2019 and no new rules were approved.

In January 2021, after voting to approve new rules months earlier, the EEOC released a set of proposed rules for incentives, but they were never published in the Federal Register after being revoked under the authority of Chair Charlotte Burrows. While the Commission is currently comprised of a 3-2 Republican Majority, Chair Burrows is a Democrat and is expected not to allow consideration of any new wellness program rules until a new Democratic commissioner is confirmed by the Senate in the summer of 2022. **Given those political dynamics, rules are unlikely to be approved prior to July 2022 at the earliest, and the Commission will likely draft substantially revised rules from the unpublished versions released earlier this year.**

COVID-19 Updates

- The Department of Health and Human Services (HHS) provided $424.7 million to over 4,200 Rural Health Clinics for COVID-19 testing and mitigation. In coming months, HHS will issue up to $35.3 million in additional funding to clinics that meet eligibility requirements. The clinics will use the funds to maintain and increase COVID-19 testing, expand access to testing for rural residents, and broaden efforts to mitigate the spread of the virus in ways tailored to their local communities.

- The Centers for Disease Control and Prevention (CDC) updated their COVID-19 frequently asked questions page. The page contains responses to a series of questions on child vaccination, vaccines and pregnancy, vaccination with underlying conditions, and ingredients in the various vaccines.

- The Department of Health and Human Services (HHS) announced a new program to invest over $3 billion from the American Rescue Plan to develop an antiviral medicine strategy for COVID-19 treatments. The plan, called the Antiviral Program for Pandemics, will bring together multiple agencies within HHS to respond to "the need for antivirals to treat COVID-19 by spurring the availability of medicines to prevent serious illness and save lives."

- Moderna announced that the federal government has purchased an additional 200 million doses of their COVID-19 vaccine. The additional doses could be used to vaccinate children or potentially as booster shots offering additional protection against COVID-19.

- The Centers for Disease Control and Prevention (CDC) updated their COVID-19 frequently asked questions page. The page contains responses to a series of questions on child vaccination,

vaccines and pregnancy, vaccination with underlying conditions, and ingredients in the various vaccines.

State Issues

Delaware

Legislative

Delaware Legislative Activity on PBMs and Provider Rates

The Delaware General Assembly held three committee hearings on health care legislation:

Senate Substitute 1 for Senate Bill 120 – SS1 places a cap on premium increases over time. By 2024 premiums cannot be increased by more than 2% plus Core CPI and 1%. In addition, by 2025 plans must spend at least 11.5% of total medical care on primary care.

House Bill 219**– PBMs / Rutledge** – HB 219 may open the PBM law to ERISA plans and includes a National Average Drug Acquisition Cost (NADAC) benchmark, reimbursement at the Wholesale Acquisition Cost (WAC), any willing pharmacy, spread pricing, and accreditation, etc.

Senate Bill 25 – **Provider Rates** - SB 25 mandates chiropractors be paid no less than Medicare rates by carriers.

State Issues

Pennsylvania

Legislative

House Committee Advances Claims Data Sharing for Groups 51-100

On Wednesday, June 16, the House Insurance Committee advanced House Bill 947 (Zimmerman, R-Lancaster). House Bill 947 would require insurance companies to provide businesses, that have between 51 to 100 employees, an aggregate on claims data for the past two years within 30 days of being requested.

The Pennsylvania House of Representatives and the Pennsylvania Senate are in session this week.

The Delaware Legislature is in session June 22-24.

The New York Legislature concluded session on June 10.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House is in session June 22-25. The U.S. Senate is in session June 21-25.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**